Immuron Executes Travelan Clinical Trial Agreement with US-based Pharmaron

Highlights:

- **Clinical Trial Master Service Agreement with US-based Pharmaron Executed**
- **Investigational New Drug (IND) application to be submitted to the U.S. Food and Drug administration (FDA)**
- **Plans in place to initiate a Controlled Human Infection Model (CHIM) clinical trial in 60 healthy volunteers in the USA**
- **Clinical Trial to examine a dosing regimen for Travelan more suited for use by the US military**
- **Infectious diarrhea is the most common illness reported by travelers**

Melbourne, Australia, October 04, 2022: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company that has developed two commercially available oral immunotherapeutic products for the treatment of gut mediated diseases, is pleased to announce that it has executed a Master Service Agreement with US-based Pharmaron CPC, Inc. a Maryland Corporation located in Baltimore USA.

The Phase II clinical trial will evaluate the efficacy of a single dose regimen of Travelan® in a controlled human infection model (CHIM) using the enterotoxigenic *Escherichia coli* (ETEC) strain H10407. Previous US military field studies have shown that for military personnel deployed in austere environments compliance is low with products dosed more than once per day. The proposed Travelan dosing regime is potentially more amenable for use in military populations. The new planned clinical study will enrol up to 60 volunteers each will be randomly assigned to receive either a once-daily dose of 1200 mg of Travelan® or placebo. This study will occur across two cohorts (n=15 Travelan® subjects and n=15 placebo subjects per cohort), as the inpatient unit can accommodate up to 30 study participants at a time. The proposed clinical development program is being funded in part by AU$6.2 (US$4.5) million award (ASX announcement January 12, 2022) from the US Department of Defense.

Immuron is currently on track to submit the Investigational New Drug (IND) application to the US Food and Drug Administration by end of 2022 and will be the sponsor of the clinical study which is planned to begin in 1H 2023 subject to FDA approval with headline results from the clinical trial expected in 2H 2023.

Infectious diarrhea is the most common illness reported by travelers visiting developing countries and among US troops deployed overseas. The morbidity and associated discomfort stemming from diarrhea decreases daily performance, affects judgment, decreases morale and declines operational readiness. The first line of treatment for infectious diarrhea is the prescription of antibiotics. Unfortunately, in the last decade, several enteric pathogens have an increasing resistance to commonly prescribed

antibiotics. In addition, travelers' diarrhea is now recognized by the medical community to result in post-infectious sequelae, including post-infectious Irritable Bowel Syndrome and several post-infectious autoimmune diseases. A preventative treatment that protects against enteric diseases, is a high priority objective for the US Military.

This release has been authorised by the directors of Immuron Limited.

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COMPANY CONTACT:

Steven Lydeamore
Chief Executive Officer
Ph: +61 (0)3 9824 5254
info@immuron.com

About Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting travelers' diarrhea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tabletized preparation of hyper immune bovine antibodies and other factors, which when taken with meals bind to diarrhea-causing bacteria and prevent colonization and the pathology associated with travelers' diarrhea. In Australia, Travelan® is a listed medicine on the Australian Register for Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travelers' Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Travelers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

About Travelers' diarrhea

Travelers' diarrhea is a gastrointestinal infection with symptoms that include loose, watery (and occasionally bloody) stools, abdominal cramping, bloating, and fever, Enteropathogenic bacteria are responsible for most cases, with enterotoxigenic *Escherichia coli* (ETEC) playing a dominant causative role. Campylobacter spp. are also responsible for a significant proportion of cases. The more serious infections with Salmonella spp. the bacillary dysentery organisms belonging to Shigella spp. and Vibrio spp. (the causative agent of cholera) are often confused with travelers' diarrhea as they may be contracted while travelling and initial symptoms are often indistinguishable.

About Immuron

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian biopharmaceutical company focused on developing and commercializing orally delivered targeted polyclonal antibodies for the treatment of inflammatory mediated and infectious diseases.

For more information visit: http://www.immuron.com

FORWARD-LOOKING STATEMENTS:

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.